

FILED

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division**

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RENEGADE TOBACCO COMPANY, INC.,)
ALTERNATIVE BRANDS, INC.,)
RENEGADE HOLDINGS, INC.,)
and)
SENECA-CAYUGA TOBACCO COMPANY,)
Plaintiffs,)
v.)
U.S. FOOD AND DRUG ADMINISTRATION,)
and)
MARGARET HAMBURG, M.D.,)
COMMISSIONER OF FOOD AND DRUGS,)
Defendants.

CLERK'S OFFICE
U.S. DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
RICHMOND, VIRGINIA
Case No. 3:10CV265

COMPLAINT

Plaintiffs Renegade Tobacco Company, Inc., Alternative Brands, Inc., Renegade Holdings, Inc., and Seneca-Cayuga Tobacco Company, by counsel, for their Complaint against Defendants the U.S. Food and Drug Administration and Margaret Hamburg, M.D., Commissioner of Food and Drugs, say as follows:

INTRODUCTION

1. This is a challenge to a regulation adopted by the U.S. Food and Drug Administration (“FDA”) on March 19, 2010. The FDA is seeking to impose draconian

restrictions on the ability of cigarette manufacturers to engage in commercial speech using their federally-registered trademarks, including brand names that have been in use for years. As explained below, the regulation violates the Free Speech Clause of the First Amendment as well as the Due Process Clause and Takings Clause of the Fifth Amendment.

2. The regulation will have perverse effects. For example, as soon as the regulation goes into effect, a small cigarette manufacturer that sells cigarettes under the brand name "Tucson" will have to stop using that brand name or face severe civil and criminal penalties, simply because the automaker Hyundai happens to sell vehicles under the same name. That small manufacturer, a plaintiff in this case, will see its business destroyed.

3. On the other hand, the big tobacco companies whose cigarette brands dominate the marketplace will be able to continue selling under their brands names *whether or not* any non-tobacco product uses the same name. This is because the FDA has provided immunity for brand names that were in effect on January 1, 1995, so long as non-tobacco products using the same name were being sold anywhere in the United States on that same date. This immunity protects most if not all of the major brand names now in use by the big tobacco companies.

4. The practical effect of this regulation will be to unfairly drive the relatively new, small cigarette manufacturers out of business by banning the use of their established brand names (and by effectively preventing them from establishing new brand names), while protecting the big tobacco companies that have long-dominated – and that continue to dominate – the cigarette market in the United States.

5. The regulation is scheduled to take effect June 22, 2010. By this lawsuit, the Plaintiffs seek to enjoin the enforcement of the regulation, both preliminarily and permanently.

6. As explained in detail below, this case meets the four-part test for issuing a preliminary injunction. *See Winter v. Natural Resources Defense Council*, 129 S. Ct. 365 (2008). First, it is clear that Plaintiffs are likely to succeed on the merits, especially since the constitutional defects in the regulation are so readily apparent. Second, Plaintiffs are likely to suffer irreparable harm in the absence of preliminary relief. Third, the balance of equities tips in Plaintiffs' favor, especially since a preliminary injunction would not cause harm to any legitimate interest the government might possibly assert. Finally, the public interest would be served by a preliminary injunction barring enforcement of this regulation.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1331, because it arises under federal law.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e), because a substantial part of the events giving rise to the claims are occurring and/or are threatening to occur in this district and in this division. The challenged regulation would prevent Plaintiffs from selling their cigarette brands in this district and division and force them to abandon existing customers in this district and division; the regulation would destroy the value of the Plaintiffs' trademarks, which are registered with the U.S. Patent and Trademark Office ("USPTO"), located in this district; and the regulation would give an unfair competitive advantage to the big tobacco companies that are headquartered and/or otherwise operate in this district and division.

PARTIES

9. Plaintiffs Renegade Tobacco Company, Inc., and Alternative Brands, Inc., are wholly owned subsidiaries of Renegade Holdings, Inc. Alternative Brands, Inc., manufactures cigarettes for distribution by Renegade Tobacco Company, Inc., as well as for other distributors.

(Collectively, these entities are referred to herein as “Renegade.”) Renegade currently manufactures and sells cigarettes in the United States, including sales in the Eastern District of Virginia, using brand names registered with the USPTO.

10. Plaintiff Seneca-Cayuga Tobacco Company (“Seneca-Cayuga”) is an unincorporated arm of the Seneca-Cayuga Tribe of Oklahoma, a federally-recognized Indian tribe. Seneca-Cayuga currently manufactures and sells cigarettes in the United States, using brand names registered with the USPTO.

11. Defendant FDA is an agency within the United States Department of Health and Human Services, which has been tasked, *inter alia*, with regulating tobacco products.

12. Defendant Margaret Hamburg, M.D., is the Commissioner of Food and Drugs. She is being sued in her official capacity.

THE REGULATION

13. The regulation at issue is 21 C.F.R. § 1140.16(a) (“the Product Name Restriction”), which was adopted by the FDA as a final rule on March 19, 2010, with an effective date of June 22, 2010. *See* 75 Fed. Reg. 13225-13232 (March 19, 2010).

14. Under 21 C.F.R. § 1140.1, products that fail to comply with the Product Name Restriction are considered “misbranded” under the Federal Food, Drug, and Cosmetic Act. Misbranded products, in turn, may be seized and destroyed, and severe civil and criminal penalties – including substantial fines and imprisonment – may be imposed on the manufacturers and sellers of such products. *See* 21 U.S.C. §§ 333 and 334.

15. The Product Name Restriction provides as follows:

Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product

whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

21 C.F.R. § 1140.16(a).

16. When it adopted the Product Name Restriction, the FDA acknowledged, in effect, that the regulation is problematic. As the agency stated: “*FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate.*” 75 Fed. Reg. 13225 (emphasis added). Nonetheless, the FDA has not amended the Product Name Restriction, nor suspended its enforcement. The regulation is still scheduled to take effect in its original form on June 22, 2010.

17. As explained below, the Product Name Restriction is problematic, *inter alia*, because of its far-reaching and unconstitutional effects, and especially because of its discriminatory effects on newer cigarette manufacturers, including Plaintiffs. This is shown by the following:

- a. First, paragraphs 18 through 28 provide six examples that explain the basic effects of the regulation on cigarette manufacturers that are not eligible for the exception related to names in use on January 1, 1995 (“the 1995 Names-In-Use Exception”)
- b. Second, paragraphs 29 through 46 explain that one or more of these basic effects applies to each of the Plaintiffs.
- c. Third, paragraphs 47 through 63 explain how the 1995 Names-In-Use Exception insulates the large cigarette manufacturers’ most lucrative brands from the effects of the regulation and discriminates against Plaintiffs and other newer cigarette companies that began in business after that date.

The Basic Effects of the Regulation

Example One – Wholly Unrelated Manufacturers

18. The Product Name Restriction is not limited to cases where a single manufacturer produces both a tobacco product and a non-tobacco product using the same trade or brand name. If a cigarette manufacturer uses, say, the name “Rustler” as the brand name of its product and a *wholly-unrelated* manufacturer uses the name “Rustler” as the brand name of a non-tobacco product, then the Product Name Restriction will require the cigarette manufacturer to abandon use of the name “Rustler.”

Example Two – No Likelihood of Confusion, Mistake or Deception

19. The Product Name Restriction applies regardless whether there is any likelihood of confusion on the part of consumers. If there are, say, both cigarettes and snow shovels bearing the brand name “Rustler,” there will be no likelihood of confusion or mistake among consumers, nor will there be any likelihood that consumers will be deceived into believing the snow shovels and cigarettes are made by the same company. Nonetheless, the Product Name Restriction will require the cigarette manufacturer to abandon use of the name “Rustler.”

Example Three – First Use and Trademark Registration

20. The Product Name Restriction applies regardless which manufacturer used the name first and regardless of trademark registration. If a cigarette manufacturer uses the name “Rustler” and a tool manufacturer *later* decides to use the name “Rustler” for snow shovels, the cigarette manufacturer will be required to abandon that name, and it will be required to do so even if the cigarette manufacturer’s use of that name was lawfully trademarked.

21. Trademark law typically would not protect cigarette manufacturers from use of the same name by a non-tobacco manufacturer because there is no likelihood that consumers

would be confused, mistaken or deceived when a cigarette and a snow shovel (or most other non-tobacco products) share the same name. Thus, a non-tobacco manufacturer could use a name already in use by a cigarette manufacturer, thereby forcing the cigarette manufacturer to abandon use of its brand name in order to comply with the Product Name Restriction. The cigarette manufacturer would have no recourse to protect its brand name under these circumstances.

22. Under the Product Name Restriction, a cigarette manufacturer's use of a brand name is not barred where a non-tobacco product using that same name has not yet entered the market; however, in those circumstances, the regulation nevertheless hangs over that cigarette manufacturer's head like the sword of Damocles, potentially falling at any moment. This is because a non-tobacco product using that name could enter the market at any time and, thereby, force the cigarette manufacturer to cease using its brand name. Thus, the Product Name Restriction has a chilling effect on the cigarette manufacturer's lawful commercial speech and deprives its brand name and associated goodwill of much or all value, thereby taking its property without just compensation.

23. The Product Name Restriction is an invitation for legal extortion by "brand name squatting" in that it would allow a non-tobacco manufacturer to apply – or threaten to apply – a pre-existing cigarette brand name to a non-tobacco product, thereby forcing the cigarette manufacturer to make financial arrangements with the non-tobacco manufacturer with respect to use of that name. A similar concern prompted Congress to enact the Anticybersquatting Consumer Protection Act, 15 U.S.C. § 1125(d), which prohibits "domain name squatting." No similar statute exist, however, to protect cigarette manufacturers from brand name squatting.

24. The Product Name Restriction also would allow the big tobacco companies to drive competitors – such as Plaintiffs and other smaller tobacco companies – out of business by

using their resources (including their subsidiaries) to produce non-tobacco products. For example, if a large tobacco company were to produce – or arrange for another entity to produce – a cookie or candy bar called “Rustler,” then the cigarette manufacturer using that name would be required to abandon it.

Example Four – Different Geographic Market

25. The Product Name Restriction applies regardless whether the tobacco product and the non-tobacco product are sold in the same geographic market. If a cigarette bearing the brand name “Rustler” is sold only in the States of Virginia and North Carolina, while a snow shovel bearing the brand name “Rustler” is sold only in the State of Alaska, the Product Name Restriction applies and the cigarette manufacturer would be required to abandon the use of the brand name “Rustler.”

Example Five – No Reference to List of Known Names

26. The Product Name Restriction is not limited to names appearing on a readily accessible list of non-tobacco products, such as a list of federally-registered trademarks. Instead, it applies to names appearing on non-tobacco products offered for sale anywhere in the economy. Thus, a cigarette manufacturer has no way of knowing with any assurance that its existing brand name – or a name it contemplates using – complies with the regulation.

Example Six – No “Grandfather” Clause for Plaintiffs

27. The Product Name Restriction is not limited to names adopted in the future by tobacco product manufacturers; it also applies to names *already in use* when the regulation was adopted on March 19, 2010. A cigarette manufacturer may have been using a trademarked brand name for five, ten, fifteen years or longer before the adoption of the regulation. Yet, if the name was not being used on both a tobacco product and a non-tobacco product as of January 1, 1995,

that cigarette manufacturer will be required to abandon use of that name if, at the time of the adoption of the regulation – or at any future time – a non-tobacco manufacturer uses the same name for a non-tobacco product.

28. In each of the foregoing examples, the Product Name Restriction not only impinges on the commercial speech of the cigarette manufacturer, it also takes and destroys the cigarette manufacturer's property interests in its product name, including any trademarks for that name and goodwill associated with that name.

These Basic Effects Impact the Plaintiffs

29. The six foregoing examples of how the Product Name Restriction will apply to cigarette manufacturers are not merely hypothetical cases. Each of the Plaintiffs is subject to one or more of those applications.

Renegade

30. Renegade's principal brand names include "Tucson," "Tracker," and "Barton." Renegade has invested significant funds in developing these brand names and accompanying goodwill and has an established property interest in these brand names. Renegade has not marketed any non-tobacco products under these brand names, nor does it intend to market any non-tobacco products under these brand names.

31. Renegade Tobacco Company, Inc. has registered the trademark "Tucson" (the "Tucson Mark") with the U.S. Patent and Trademark Office ("USPTO"), Serial No. 76156510. The application for the Tucson Mark was filed on October 31, 2000, and the Tucson Mark was registered as of September 7, 2004, for use with the following goods and services: "cigarettes." The Tucson Mark registration remains in effect as of the date of the filing of this Complaint.

32. Renegade Tobacco Company, Inc. has registered the trademark "Tracker" (the "Tracker Mark") with the USPTO, as Serial No. 76525463. The application for the Tracker Mark was filed on June 25, 2003, and the Tracker Mark was registered as of March 1, 2005, for use with the following goods and services: "cigarettes." The Tracker Mark registration remains in effect as of the date of the filing of this Complaint.

33. Renegade Tobacco Company, Inc. has registered the trademark "Barton" (the "Barton Mark") with the USPTO, as Serial No. 76547561. The application for the Barton Mark was filed on September 30, 2003, and the Barton Mark was registered as of December 4, 2007, for use with the following goods and services: "tobacco products, namely, cigarettes." The Barton Mark registration remains in effect as of the date of the filing of this Complaint.

34. Each of the foregoing Renegade brand names was not being used on a cigarette product on January 1, 1995. Accordingly, Renegade is subject to the Product Name Restriction and is not eligible for the 1995 Names-In-Use Exemption for any of its principal cigarette brands.

35. On information and belief, one or more non-cigarette manufacturers now use the names "Tucson," "Tracker" and "Barton" for their non-tobacco products. For example, according to the USPTO:

- a. the trademark "Tucson" is used on, *inter alia*, automobiles (Serial No. 78295857);
- b. the trademark "Tracker" is used on, *inter alia*, handheld computers used for playing bingo (Serial No. 78844526); and
- c. the trademark "Barton" is used on, *inter alia*, alcoholic beverages (Serial No. 75699796).

36. Effective June 22, 2010, Renegade will be in violation of the Product Name Restriction unless it abandons the Tucson Mark, Tracker Mark and Barton Mark. Thus, these three Renegade trademarks provide real life illustrations of how the Product Name Restriction will result in damage to cigarette manufacturers, as explained in **Examples One, Two and Six**, Paragraphs 18, 19 and 27, *supra*.

37. Additionally, Renegade has registered the trademark "Diamond Jack" (the "Diamond Jack Mark") with the USPTO, as Serial No. 76563073. The application for the Diamond Jack Mark was filed on December 3, 2003, and the Diamond Jack Mark was registered as of January 22, 2008, for use with the following goods and services: tobacco products, namely, cigarettes. The Diamond Jack Mark registration remains in effect as of the date of the filing of this Complaint.

38. Renegade intends to use Diamond Jack as a brand name for a new line of cigarettes. No non-tobacco product using the "Diamond Jack" appears on the USPTO trademark registry. Nonetheless, should another entity decide to use the name "Diamond Jack" for a non-tobacco product in the future, Renegade would be forced to abandon the Diamond Jack Mark. Thus, the Diamond Jack Mark provides a real life illustration of how the Product Name Restriction will result in damage to cigarette manufacturers, as explained in **Example Three**, Paragraphs 20 - 24, *supra*.

39. Additionally, even though no other use of the Diamond Jack Mark appears on the USPTO trademark registry, it is possible that another entity already is using the mark on goods sold in an area of the country where Renegade does little or no business. If this is the case, then the Diamond Jack Mark will run afoul of the Product Name Restriction, even though Renegade did not know, and could not have known, of such other use of the Diamond Jack name. Thus,

the Diamond Jack Mark also provides a real life illustration of how the Product Name Restriction will result in damage to cigarette manufacturers, as explained in **Examples Four and Five**, Paragraphs 25 - 26, *supra*.

40. Renegade also serves as a contract manufacturer, manufacturing cigarettes for labeling and sale by other companies. These companies' brand names, all of which have been established after January 1, 1995, also are likely to run afoul of the Product Name Restriction. Consequently, Renegade stands to lose even the contract manufacturing portion of its business.

Seneca-Cayuga

41. Seneca-Cayuga's principal brand is "Skydancer." Seneca-Cayuga has invested significant funds in developing the "Skydancer" brand name and accompanying goodwill and has an established property interest in this brand name. Seneca-Cayuga has not marketed any non-tobacco products under the Skydancer brand name, nor does it intend to market any non-tobacco products under such brand name.

42. Seneca-Cayuga has registered the trademark "Skydancer" (the "Skydancer Mark") with the USPTO, as Serial No. 78172235. The registration was filed on October 8, 2002, and the Skydancer Mark was registered as of March 21, 2006, for use with the following goods and services: "cigarettes, cigars, cigarette lighters not of precious metal, matches." The Skydancer Mark registration remains in effect as of the date of the filing of this Complaint.

43. The Skydancer Mark was not being used on a cigarette product on January 1, 1995. Accordingly, Seneca-Cayuga is subject to the Product Name Restriction and is not eligible for the 1995 Names-In-Use Exemption for its "Skydancer" cigarette brand.

44. Seneca-Cayuga is aware of a business, wholly-independent of Seneca-Cayuga, that uses and/or has used the name "Skydancer" on a non-tobacco product, namely, inflatable

action figures. Other businesses also might choose to use the “Skydancer” name for other non-tobacco, such as kites, various aeronautical products or almost anything else. Seneca-Cayuga would have no legal recourse to prevent a non-tobacco manufacturer from using the “Skydancer” name if the use is not likely to cause confusion or mistake, or to deceive. Indeed, if the non-tobacco business did not apply for a federal trademark, Seneca-Cayuga might not even know that the name was being used by someone else. Thus, Seneca-Cayuga is subject to the harms set forth above in **Examples One, Two, Three, Five and Six**, Paragraphs 18, 19, 20 - 24, 26 and 27, *supra*.

All Plaintiffs

45. In order to comply with the Product Name Restriction and still sell cigarettes as of June 22, 2010, Plaintiffs Renegade and Seneca-Cayuga will be forced to incur substantial expenses in advance of that date in various matters, including but not limited to (a) finding names that are both suitable from a marketing perspective and not forbidden by the regulation, (b) obtaining the necessary certifications and approvals of those brand names from the States wherein the cigarettes will be sold, (c) obtaining packaging approval from the Federal Trade Commission, see 15 U.S.C. §§ 1331, *et seq.*, and (d) ordering supplies of cigarette packaging and related materials. It is highly unlikely that these steps could be achieved, especially given the wide sweep of the regulation and the need to obtain government approvals.

46. Alternatively, in order to have any chance of remaining in business, Plaintiffs Renegade and Seneca-Cayuga will be forced to stand on their constitutional rights, as set forth below, and continue using their existing brand names after June 22, 2010, thereby risking prosecution as well as both civil and criminal penalties.

The Effects of the 1995 Names-In-Use Exception

47. The Product Name Restriction does not treat all cigarette manufacturers even-handedly. The 1995 Names-In-Use Exception grants immunity to any cigarette brand name that was in use as of January 1, 1995, so long as the same name was also being used on a non-tobacco product sold in the United States on that date. *See* 21 C.F.R. § 1140.16(a).

48. The 1995 Names-In-Use Exception applies regardless whether the non-tobacco product ceased to be sold in the United States after January 1, 1995, and regardless whether another non-tobacco product began to use that name after that date.

49. The 1995 Names-In-Use Exception protects a cigarette manufacturer regardless whether the non-tobacco product was being marketed on January 1, 1995, by another party or by that same cigarette manufacturer.

50. In 1995, the cigarette market in the United States was dominated by four large tobacco companies: Philip Morris Inc., R.J. Reynolds Tobacco Co., Brown & Williamson Tobacco Corp. and Lorillard Tobacco Co. In 1995, these four companies collectively accounted for 97.8 percent of the cigarette market in the United States.

51. In 2009, these same large tobacco companies collectively accounted for 89.5 percent of the cigarette market in the United States. (The number of these dominant manufacturers was reduced from four to three when Brown & Williamson merged with R.J. Reynolds in July 2004, creating a new parent company, Reynolds American, Inc.).

52. On information and belief, at the time of the adoption of the Product Name Restriction by the FDA and at the time of the filing of this Complaint, these same large tobacco companies continued to account for approximately 90 percent of the cigarette market in the United States

53. These three large tobacco companies sell cigarettes under the following principal brand names, all of which names were already in use on January 1, 1995.

- a. **Philip Morris Inc.:** Marlboro, Virginia Slims, Merit, Parliament, Benson & Hedges, Cambridge and Basic as well as L&M, Chesterfield, and Lark. (the last three brands having been purchased by Philip Morris from Liggett Vector Brands Inc. in 1999).
- b. **Reynolds American, Inc.:** Camel, Winston, Salem, Doral, and Misty (formerly R.J. Reynolds brands) as well as GPC, Kool, Pall Mall, Capri, Lucky Strike, and Viceroy (formerly Brown & Williamson brands).
- c. **Lorillard Tobacco Co.:** Newport, Maverick, Old Gold, Kent, True, Satin, and Max.

54. As reported by the Centers for Disease Control ("CDC"), the six top-selling brands in the United States and their respective market shares are as follows:

Marlboro	41.0%
Newport	9.7%
Camel	6.7%
Doral	3.8%
Basic	3.5%
Winston	3.2%

See http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/brand_preference/index.htm (reporting data from 2008). As reported by the CDC, these six top-selling brands collectively account for 67.9 percent of the cigarette market in the United States, and they include the three most heavily advertised brands, Marlboro, Newport and Camel. *Id.* Yet, each

of these six top-selling brands is protected by the 1995 Names-In-Use Exception and, thus, is not subject to the restrictions of the Product Name Restriction.

55. In some cases, the “same name” non-tobacco product was being marketed in 1995 by a large tobacco company as part of its brand promotion campaign. In other cases, the “same name” non-tobacco product was being marketed in 1995 by a company that was wholly-independent of any tobacco company. Examples of such marketing include the following:

- a. In addition to using the “Marlboro” name on its cigarettes, Philip Morris Inc., registered the “Marlboro” name from 1982 until 2002 for use on “Men’s and Women’s Clothing – Namely, Coats, Shirts, Hats, Vests and Neckerchiefs.” *See* Trademark Serial No. 73253754. (Philip Morris also has acquired and continues to hold a separate trademark for “Marlboro” brand clothing. *See* Trademark Serial No. 71494855). Because “Marlboro” clothing and “Marlboro” cigarettes were both being sold in the United States on January 1, 1995, the “Marlboro” cigarette brand is not subject to the Product Name Restriction.
- b. “Newport” has been a registered trademark of a manufacturer of hip braces from 1993 to the present. *See* Trademark Serial No. 74350881. Because “Newport” hip braces and “Newport” cigarettes were both being sold in the United States on January 1, 1995, the “Newport” cigarette brand is not subject to the Product Name Restriction.
- c. Similarly, a search of the database of the USPTO reveals other instances where a non-tobacco product, bearing the same name as a top-selling cigarette, was being sold in the United States on January 1, 1995, thus

giving the large tobacco companies the benefit of the 1995 Names-In-Use Exception. *See, e.g.*, “Camel” glassware (Trademark Serial No. 74115594), “Doral” sedatives and sleep aids (Trademark Serial No. 73813871), “Basic” surgical shoe covers (Trademark Serial No. 74491696), and “Winston” automobile tires (Trademark Serial No. 72378552).

56. Although the USPTO trademark registry reveals many instances where the same name was used on both a cigarette as well as a non-tobacco product sold in the United States on January 1, 1995, the FDA regulation does not require the name of the non-tobacco product to have been registered with USPTO – or anywhere else – in order for a cigarette manufacturer to invoke the 1995 Names-In-Use Exception. On information and belief, in 1995, there were many instances where the name used on a national cigarette brand also was used, independently, on a non-tobacco product sold in a local or regional market and not registered with the USPTO.

57. On information and belief, the majority (and perhaps all) of the cigarette brand names currently used by the three large tobacco companies are protected by the 1995 Names-In-Use Exception, thereby insulating approximately 90 percent of the current cigarette market in the United States from the Product Name Restriction.

58. The Product Name Restriction is especially egregious because it protects the four large tobacco companies from the consequences of their past unlawful conduct – conduct in which the newly-formed, smaller cigarette manufacturers did not participate.

59. In 1998, because of their history of unlawful conduct – including, but not limited to fraud, negligent advertising and violation of various state consumer protection statutes – the four large tobacco companies listed in Paragraph 50 were forced to enter into a settlement

agreement with the Attorneys General of 46 States, the District of Columbia and six territories (the “Master Settlement Agreement”).

60. Under the Master Settlement Agreement, those large tobacco companies are obligated to make substantial payments to the States totaling \$206 billion (and billions more in perpetuity). Those large tobacco companies also agreed to certain restrictions on their ability to advertise their products.

61. Following the adoption of the Master Settlement Agreement, a number of new cigarette companies entered the marketplace. Having not engaged in the misconduct that forced the large tobacco companies to enter into the Master Settlement Agreement – and not having the same financial obligations – these small cigarette companies have been able to compete with the large tobacco companies so as to find a niche in the marketplace.

62. The principal effect of the Product Name Restriction will be to protect the large tobacco companies from competition by (a) destroying the ability of the new, small cigarette companies to market their products using their current brand names, (b) preventing the new, smaller cigarette companies from building brand identities using new names, and (c) protecting the ability of the large, pre-1995 tobacco companies to market their major brands.

63. In other words, the Product Name Restriction will assure the large tobacco companies continued dominance in the marketplace, while driving from the marketplace their small competitors. This is not a legitimate exercise of the FDA’s authority.

COUNT I – FREE SPEECH

64. Plaintiffs re-allege, as if set out in full, the allegations of Paragraphs 1 through 63 hereof.

65. The Plaintiffs' selection and use of brand names to identify and advertise their products constitutes commercial speech and, as such, is protected by the Free Speech Clause of the First Amendment. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001) ("[S]o long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information.").

66. A government regulation of commercial speech is invalid under the First Amendment if the regulation fails to satisfy the test set forth in *Central Hudson Gas Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980).

67. Under the *Central Hudson* test, the first question is whether the speech concerns lawful activity and is not misleading. The Plaintiffs' selection and use of brand names to identify and advertise their products concerns a lawful activity (manufacture and sale of tobacco products) and is not misleading, nor does the Product Name Restriction require that a brand name be misleading in order for that regulation to apply.

68. Given the lawfulness of the activity and the lack of misleading speech, government regulation of the commercial speech at issue violates the *Central Hudson* test unless the government can show that (a) the government has a substantial interest in regulating the speech, (b) the regulation directly advances the government's substantial interest, and (c) the regulation is not more extensive than necessary to serve that interest.

69. The Product Name Restriction violates the *Central Hudson* test – and, thus, is unconstitutional – because the government does not have a substantial interest in regulating the speech at issue – *i.e.* the use of otherwise lawful brand names of cigarettes, including trademarked brand names. Alternatively, even if the government has a substantial interest in

regulating the speech at issue, the regulation does not directly advance that substantial interest, and/or the regulation is more extensive than necessary to serve that interest.

70. It is the government's burden to show that the Product Name Restriction meets each of the elements of the *Central Hudson* test; it is not the Plaintiffs' burden to show otherwise.

71. The government cannot make the showing required by *Central Hudson* because, *inter alia*, of the immunity that the 1995 Names-In-Use Exception gives to the brands that dominate the United States cigarette market. *See Paragraphs 47 - 63, supra.*

- a. First, given the breadth of the exception, the government's interest in regulating the speech actually subject to the regulation cannot be considered substantial.
- b. Second, given the small percentage of the cigarette market that would be subject to the Product Name Restriction, the regulation does not directly advance any interest the government might assert.
- c. Finally, by obliterating the ability of smaller tobacco companies to maintain their brands (while giving immunity to the dominant brands), the regulation is more extensive than necessary to serve any interest the government might assert.

72. Even if the Product Name Restriction were to meet the *Central Hudson* test, it still would be invalid because it fails to meet other First Amendment tests that are applicable to this case.

73. Given the exception for brand names in effect on January 1, 1995, the Product Name Restriction constitutes unconstitutional discrimination based on the identity of the speaker and/or the content of the message.

74. The Product Name Restriction fails to comply with strict scrutiny in that it fails to advance a compelling government interest and/or is not narrowly tailored to meet any such interest.

75. As explained above, a cigarette manufacturer cannot know with reasonable certainty whether a name it selects satisfies the regulation. *See Paragraphs 26, *supra*.* Thus, the Product Name Restriction violates the First Amendment because its vagueness chills lawful commercial speech, and the regulation is otherwise void for vagueness.

76. The Product Name Registration is invalid on its face because the regulation is impermissibly overbroad. The regulation's unconstitutional applications are "substantial" in number when judged in relation to any "plainly legitimate sweep" that the regulation may have.

77. For the foregoing reasons, the Product Name Restriction is invalid both on its face and as applied to Plaintiffs and their brands.

COUNT II – DUE PROCESS (VIOLATION OF EQUAL PROTECTION)

78. Plaintiffs re-allege as if set out in full, the allegations of Paragraphs 1 through 77 hereof.

79. The Due Process Clause of the Fifth Amendment contains an equal protection component applicable against the federal government and equivalent to the protections applicable against the States under the Equal Protection Clause of the Fourteenth Amendment. *See Bolling v. Sharpe*, 347 U.S. 497, 499 (1954); *Buckley v. Valeo*, 424 U.S. 1, 93 (1976) (*per curiam*).

80. The Product Name Restriction provides unequal treatment in that it establishes different rules for different cigarette manufacturers depending whether their cigarette brand names (and the names of non-tobacco products) were in use on January 1, 1995.

81. Because the unequal treatment found in the Product Name Restriction implicates fundamental rights, the regulation must be judged by strict scrutiny. That is to say, the regulation is unconstitutional unless the government can show that it serves a compelling interest and is narrowly tailored to achieve that interest.

82. The unequal treatment found in the Production Brand Restriction does not serve a compelling governmental interest and/or is not narrowly tailored to achieve any such interest. Thus, the Product Name Restriction violates the equal protection aspect of the Due Process Clause.

83. In the alternative, even if strict scrutiny were not applied, the unequal treatment found in the Product Name Restriction still would violate the equal protection aspect of the Due Process Clause because it fails under any other level of equal protection scrutiny that the Court may deem to be applicable.

84. The regulation fails under intermediate scrutiny because the unequal treatment does not further an important government interest and/or is not substantially related to that interest.

85. The regulation fails under the rational basis test because unequal treatment does not serve a legitimate government interest and/or is not rationally related to any such interest.

COUNT III – DUE PROCESS (DEPRIVATION OF PROPERTY)

86. Plaintiffs re-allege as if set out in full, the allegations of Paragraphs 1 through 85 hereof.

87. At the time of the adoption of the Product Name Restriction on March 19, 2010, cigarette manufacturers – including Plaintiffs – enjoyed a statutory and/or common law right to use their trademarked brand names and/or other existing brand names on their products, those statutory rights being provided, *inter alia*, by federal trademark law.

88. Said statutory rights and/or common law rights constitute a form of property.

89. Said property is valuable, *inter alia*, because it allows brand owners to identify their products in a highly competitive marketplace, to communicate with retailers and consumers with respect to the origin and quality of their products, and to build goodwill and brand loyalty among distributors, retailers and consumers – all of which results in economic benefit to the brand owners.

90. By prohibiting certain cigarette manufacturers – including Plaintiffs – from using their trademarked brand names and/or other existing brand names on their products, the Product Name Restriction has deprived and/or threatens to deprive them of their property, thereby causing them great loss and damage, including but not limited to the loss of the right to use those names and the loss of the goodwill that accompanies those names.

91. Said deprivation of property has occurred without due process of law and in violation of the Due Process Clause of the Fifth Amendment.

92. The regulation also violates the Due Process Clause because a cigarette manufacturer cannot know with reasonable certainty whether a name he selects satisfies the regulation. *See Paragraphs 26, supra.* The regulation therefore “fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits,” and/or “authorizes or even encourages arbitrary and discriminatory enforcement.” *Hill v. Colorado*, 530 U.S. 703, 732 (2000). Thus, the regulation is void for vagueness.

COUNT IV – TAKING WITHOUT JUST COMPENSATION

93. Plaintiffs re-allege as if set out in full, the allegations of Paragraphs 1 through 92 hereof.

94. Neither the FDA nor any other agency or law of the federal government has provided Plaintiffs any compensation whatsoever for the loss of their property, much less just compensation.

95. The Product Name Restriction takes from cigarettes manufacturers – including Plaintiffs – their right to use trademarked brand names and/or other existing brand names on their products and, in so doing, also takes from them the goodwill that accompanies those names.

96. The Supreme Court has identified three factors for courts to consider in assessing whether a taking of property has occurred so as to bring the Takings Clause into play: (a) the character of the governmental action; (b) its economic impact; and (c) its interference with reasonable investment-backed expectations. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005 (1984); *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).

97. The force of any one of these three factors may be “so overwhelming . . . that it disposes of the takings question.” *Ruckelshaus*, 467 U.S. at 1005.

98. In the case at bar, each of the three factors standing alone, provides sufficient reason why the Product Name Restriction violates the Takings Clause.

99. With respect to the first factor, the character of the government action provides sufficient reason why the Product Name Restriction violates the Takings Clause. For example, in its application to Plaintiffs – and other cigarette manufacturers – the Product Name Restriction

is not rationally related to any legitimate government objective, especially given the 1995 Names-In-Use Exception.

100. With respect to the second factor, the economic impact of the government action provides sufficient reason why the Product Name Restriction violates the Takings Clause. For example, the Product Name Restriction wholly extinguishes the value of the brand names that it prohibits as well as the goodwill that accompanies those names.

101. With respect to the third factor, the regulation's interference with reasonable investment-backed expectations provides sufficient reason why the Product Name Restriction violates the Takings Clause. The Product Name Restriction wholly deprives cigarette manufacturers – including Plaintiffs – of their reasonable, investment-backed expectations in continuing to use their brand names and accompanying goodwill. For example, at the time of their investments in their names, the Plaintiffs could not have reasonably anticipated that the FDA would have adopted a regulation taking their use of their brand names illegal.

102. Alternatively, the three factors, taken together, provide sufficient reason why the Product Name Restriction violates the Takings Clause.

COUNT V – *ULTRA VIRES*

103. Plaintiffs re-allege as if set out in full, the allegations of Paragraphs 1 through 102 hereof.

104. This is not the first time the FDA has adopted a regulation purporting to restrict the use of product names on cigarettes. In 1995, the FDA gave notice of its intent to adopt such a regulation. *See* 60 Fed. Reg. 41314, 41374 (August 11, 1995). In 1996, the FDA adopted the proposed regulation. *See* 61 Fed. Reg. 44396, 44616 (August 28, 1996) (adopting Final Rule).

This 1996 Regulation, 21 C.F.R. § 897.16(a), used exactly the same text found in the 2010 regulation now at issue.

105. In 2000, the 1996 regulation restricting use of product names on cigarettes – along with many other tobacco related regulations – was struck down when the U.S. Supreme Court decided that the FDA had no authority to regulate tobacco. *See Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000).

106. In 2009, Congress adopted new legislation giving the FDA authority to regulate tobacco. *See P.L. 111-31* (June 22, 2009), now codified at 15 U.S.C. §§ 1333 *et seq.* As part of this act, Congress directed the FDA to adopt a regulation “identical in its provisions” to the regulations adopted by the FDA in 1996. *See 75 Fed. Reg. 13225, 13229* (March 19, 2010). At the same time, Congress directed the FDA to take into account the decision of the U.S. Supreme Court in *Lorillard Tobacco*. *See id.* at 13226.

107. In deciding *Lorillard Tobacco*., the Supreme Court said, “[S]o long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information.” 533 U.S. at 571.

108. The 1996 FDA regulation contained a “grandfather” clause that gave certain protections to names in use at the beginning of the calendar year when notice of the regulation was first given to the public. If the FDA had followed the same approach in its current regulation, it would have used January 1, 2009 as the date for giving “grandfather” clause protection to names in use. Instead, in its new regulation, the FDA leapt all the way back to January 1, 1995 – a date *fourteen years* earlier.

109. Although the new regulation uses the *same text* as the earlier regulation, it does so with a radically different effect and, thus, it is not “identical in its provisions” within any reasonable understanding of that phrase. This is especially so because the new regulation takes and destroys the value of those brand names – and associated good will – developed by small cigarette manufacturers in reliance on the Supreme Court’s decision in *Brown & Williamson*. The 1996 regulation had no such effect.

110. By interpreting P.L. 111-31 to require adoption of a regulation with the *same text* as the 1996 regulation, rather than adoption of a regulation with the *same effects* as the 1996 regulation, the FDA acted arbitrarily and capriciously, and its interpretation is impermissible.

111. In addition, by re-adopting its earlier product name restrictions, the FDA disregarded the instruction from Congress taking into account the Supreme Court’s decision in *Lorillard Tobacco*.

112. For the foregoing reasons, the FDA exceeded its authority when it adopted the Product Name Restriction at issue in this case, and the regulation should be stricken as *ultra vires*.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask the Court to grant them the following relief:

1. A preliminary injunction barring enforcement of the Product Name Restriction, 21 CFR 1140.16(a), pending the final resolution of this case;
2. A declaration that the Product Name Restriction, 21 C.F.R. § 1140.16(a), is unconstitutional in that it violates the Free Speech Clause of the First Amendment, the Due Process Clause of the Fifth Amendment and/or the Takings Clause of the Fifth Amendment;

3. A permanent injunction barring enforcement of the Product Name Restriction, 21 C.F.R. § 1140.16(a); and
4. Such other and/or additional relief as equity and the nature of the case may require, including but not limited to the award of attorneys' fees and costs.

Respectfully submitted,

RENEGADE TOBACCO COMPANY,
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